IN THE CLAIMS

1. (Currently Amended) An immunoassay for assaying a soluble target antigen or antibody present in a whole blood sample, comprising the steps of:

(a) mixing the whole blood sample with insoluble carrier particles which are sensitized with an antigen against the soluble target antibody or an antibody against the soluble target antigen, wherein said particles are smaller than erythrocytes, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

(b) introducing the immune agglutination reaction mixture to a flow cell, irradiating the particles passing through the flow cell with laser light, and detecting scattered light generated thereby;

(c) setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to intensity of the scattered light;

(d) distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the intensity of the scattered light detected in the step (b), in reference to the first and second threshold values set in the step (c);

(e) calculating a degree of agglutination from the number of the unagglutinated insoluble carrier particles and the number of the agglutinated insoluble carrier particles;

(f) converting the degree of agglutination into a concentration of the soluble target antigen or antibody in the whole blood sample using a calibration curve showing a relationship between a degree of agglutination and a concentration of a soluble target antigen or antibody; and

(g) obtaining a corrected concentration of the soluble target antigen or antibody based on the following formula:

$$C = CO / (1-B-A) (1-B/A),$$

wherein C is a corrected concentration, CO is the concentration of the soluble target antigen or antibody present in the whole blood sample, B is the number of blood cells and A is a constant.

2-4. (Cancelled)

5. (Currently Amended) An immunoassay for assaying a soluble target antigen or antibody present in a whole blood sample, comprising the steps of:

(a) mixing the whole blood sample with insoluble carrier particles which are sensitized with an antigen against the soluble target antibody or an antibody against the soluble target antigen, wherein said particles are smaller than erythrocytes, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

(b) introducing the immune agglutination reaction mixture to a flow cell, irradiating the particles passing through the flow cell with laser light, and detecting scattered light generated thereby;

(c) setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to intensity of the scattered light;

(d) distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the intensity of the scattered light detected in the step (b), in reference to the first and second threshold values set in the step (c);

(e) calculating a degree of agglutination from the number of the unagglutinated insoluble carrier particles and the number of the agglutinated insoluble carrier particles;

(f) converting the degree of agglutination into a concentration of the soluble target antigen or antibody in the whole blood sample using a calibration curve showing a relationship between a degree of agglutination and a concentration of soluble target antigen or antibody; and

(g) obtaining a mean corpusculer volume (MCV) in the whole blood sample, wherein the concentration of the soluble target antigen or antibody present in the whole blood sample is corrected according to the MCV measurement and the number of blood cells.

6. (Previously Presented) The immunoassay according to claim 5, wherein the mean corpusculer volume (MCV) is obtained from the scattered lights detected in the step (b), in reference to the threshold values set in the step (c).

7. (Previously Presented) The immunoassay according to claim 5, wherein correction according to the MCV measurement and the number of blood cells is made by use of the following formula:

$$C = CO / \{1 - (B/A) \times (MCV / D)\},$$

wherein C, CO, A and B are the same as defined above, MCV is the MCV measurement of the sample and D is a constant.

8. (Previously Presented) The immunoassay according to Claim 1, wherein the scattered light is forward scattered light.

9. (Previously Presented) The immunoassay according to Claim 1, wherein the size of the insoluble carrier particles is 0.1 μm to 1.0 μm.

10. (Previously Presented) The immunoassay according to Claim 1, wherein, in the step (a), the temperature is from 20 to 50°C and the time is from 15 seconds to 20 minutes.

11-12. (Cancelled).

13. (Currently Amended) An immunoassay apparatus for assaying a soluble target antigen or antibody present in a whole blood sample, comprising:

a reaction part for mixing the whole blood sample with insoluble carrier particles which are sensitized with an antigen against the soluble target antibody or an antibody against the soluble target antigen, wherein said particles are smaller than erythrocytes, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

a dispenser for introducing the resulting immune agglutination reaction mixture to a flow cell,

a laser for irradiating the particles passing through the flow cell with laser light,

a photo acceptance unit for detecting scattered light generated thereby,

a signal processor for converting the scattered light to an electrical signal, and

a data processor configured for setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to the signal based on intensity of the scattered light; for distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values; for calculating a degree of agglutination from the number of the unagglutinated insoluble carrier particles and the number of the agglutinated insoluble carrier particles; for converting the degree of agglutination into a concentration of the soluble target antigen or antibody in the whole blood sample using a calibration curve showing a relationship between a degree of agglutination and a concentration of a soluble target antigen or antibody; and for obtaining a corrected concentration of the soluble target antigen or based on the following formula:

$$C = CO / (\cancel{1 - B - A}) \ (1-B/A),$$

wherein C is a corrected concentration, CO is the concentration of the soluble target antigen or antibody present in the whole blood sample, B is the number of blood cells and A is a constant.

14. (Cancelled)

15. (Previously Presented) The immunoassay according to Claim 5, wherein the scattered light is forward scattered light.

16. (Previously Presented) The immunoassay according to Claim 5, wherein the size of the insoluble carrier particles is 0.1 μm to 1.0 μm.

17. (Previously Presented) The immunoassay according to Claim 5, wherein, in the step (a), the temperature is from 20 to 50 °C and the time is from 15 seconds to 20 minutes.

18. (Previously Presented) An immunoassay apparatus for assaying a soluble target antigen or antibody present in a whole blood sample, comprising:

a reaction part for mixing the whole blood sample with insoluble carrier particles which are sensitized with an antigen against the soluble target antibody or an antibody against the soluble target antigen, wherein said particles are smaller than erythrocytes, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

a dispenser for introducing the resulting immune agglutination reaction mixture to a flow cell,

a laser for irradiating the particles passing through the flow cell with laser light,

a photo acceptance unit for detecting scattered light generated thereby,

a signal processor for converting the scattered light to an electrical signal, and

a data processor, wherein said data processor is:

configured for setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to the signal based on intensity of the scattered light;

configured for distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values;

configured for calculating a degree of agglutination from the number of the unagglutinated insoluble carrier particles and the number of the agglutinated insoluble carrier particles;

configured for converting the degree of agglutination into a concentration of the soluble target antigen or antibody in the whole blood sample using a calibration curve showing a relationship between the degree of agglutination and a concentration of a soluble target antigen or antibody; and

configured for obtaining a mean corpusculer volume (MCV) in the whole blood sample,

wherein the concentration of the soluble target antigen or antibody present in the whole blood sample is corrected according to the MCV measurement and the number of blood cells.

19. (Previously Presented) The immunoassay apparatus according to Claim 13, wherein the size of the insoluble carrier particles is 0.1 μm to 1.0 μm.

20. (Previously Presented) The immunoassay apparatus according to Claim 18, wherein the size of the insoluble carrier particles is 0.1 μm to 1.0 μm.